DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

g1847d

October 11, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 – 08

Vern Donnell
Service Unit Director
Pine Ridge Reservation Comprehensive Health Center
P.O. Box 1201
Pine Ridge, South Dakota 57770

Dear Mr. Donnell:

On September 11, 2001, the Food and Drug Administration (FDA) inspected your mammography facility (FDA certification #185470). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Repeat Level 2 and Repeat Level 3 findings were documented at your facility:

Level 1 Non-Compliance:

1. Site failed to produce documents verifying that the interpreting physician, ~~~~ met the initial requirement of being certified in the appropriate specialty by a FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.

Repeat Level 2 Non-Compliance:

2. Site failed to produce documents verifying that the interpreting physician, ~~~~ , met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

Repeat Level 3 Non-Compliance:

3. The required personnel qualification documents were not available during the inspection.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

A "repeat" non-compliance indicates that the same type of violation was cited during the previous inspection. For repeat non-compliances involving personnel issues, they may or may not involve the same individual(s) as cited in the previous year.

Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. For physicians the "Continuing" requirements include either the lack of appropriate CME/24 months or Number of Interpretations/36 months. Requirements for re-qualification are listed in the Final Regulation that became effective on April 28, 1999.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain

general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at *http://www.fda.gov/cdrh/mammography/index.html.*

If you have specific questions about mammography facility requirements, or about the content of this letter, please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Sharon K. Thoma

Sharon K. Thoma
Acting Director
Minneapolis District

jeh
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